REMARKS

Applicants and their representatives thank the Examiner for her time and courtesy in conducting the Interview of November 10, 2004. The substance of Interview is summarized by the above amendments and following remarks in addition to the Examiner's Interview Summary form, of record.

Pursuant to the discussion at the Interview, the claims have been amended to more specifically recite the methods of treatment. Further, all the claims now characterize the drospirenone by its being "micronized"), by its surface area or by its dissolution profile.

The claims are not obvious over the combined teachings of Lignieres and Fuhrmann, relied upon in the Final Office Action. The evidence, particularly the 37 C.F.R. §1.132 declaration of Dr. Lipp, demonstrates that one of ordinary skill in the art would not have been motivated to use micronized drospirenone (or drospirenone having a rapid dissolution profile as defined in some claims or the high surface area as defined in some claims) in a drug for oral administration. The Lipp Declaration is supplemented by a Declaration of Dr. Funke which more specifically addresses the details of the Nickisch prior art, which is a primary basis for the above-mentioned lack of motivation argument. The Funke Declaration is a copy of one submitted in related application Ser. No. 09/654,227, now U.S. Patent No. 6,787,531, but is equally applicable here.

In the Final Office Action, Dr. Lipp's Declaration was alleged to be insufficient. Those allegations are refuted as follows.

First, it was stated that "none of the fomulation[s] recite the actual micron sizes of DRSP." However, all the claims do characterize the drospirenone in a definite manner which distinguishes the prior art, i.e., by size, e.g. micronized, by surface area or by dissolution profile. The "micronized" term has a known meaning in the art. This is demonstrated, for

example, by its routine use in many of the references of record. Each of the forms of drospirenone recited in the instant claims would have been expected by one of ordinary skill in the art to give the rapid dissolution which would have been expected by one of ordinary skill in the art to lead to undesired isomerization in the stomach, as established by the Lipp and Funke declarations.

Second, contrary to the statement in the Office Action, applicants have not argued that the Lipp declaration shows an "unexpected finding that micronization of DRSP improves bioavailability," and have not submitted "unexpected results." The Lipp and Funke declarations provide no *in vivo* data either way on bioavailability. Applicants' position is that the record evidences a lack of motivation to orally administer drospirenone in any of the forms stated in the instant claims because of Nickisch's teaching of the acid-catalyzed isomerization to inactive form. In the absence of such motivation, unexpected results are not required to show patentability.

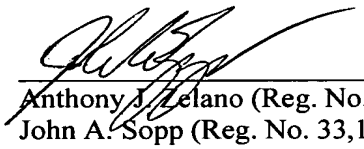
Third, the Office Action equates enhanced bioavailability with increased dissolution. But it is clear from the above discussion and the Lipp and Funke declarations that this is not always the case. If enhanced dissolution facilitates isomerization to an inactive form before a drug becomes bioavailable, then a decrease in bioavailability would be expected. The Office Action refers to applicants' statement in the specification: "To ensure good bioavailability of the compound, it is therefore advantageously provided in a form that promotes rapid dissolution thereof." This finding by applicants was not known in the art and, in fact, was contrary to the expectations in the art, as previously discussed. Use of applicants' own disclosure of the invention to support a rejection against them is improper.

It is submitted that the claims are in condition for allowance. However, the Examiner

is kindly invited to contact the undersigned to discuss any unresolved matters.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,



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